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A study comparing intermittent with continuous treatment with BTK inhibitors in chronic lymphocytic leukaemia (CLL)

Submission date
21/06/2022

Recruitment status
Recruiting

Registration date
27/06/2022

Overall study status
Ongoing

Last Edited
07/07/2025

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-ibrutinib-with-and-without-treatment-breaks-for-chronic-lymphocytic-leukaemia-static

Background and study aims
Ibrutinib is one of a group of drugs for chronic lymphocytic leukaemia (CLL) called targeted drugs. Targeted drugs, including ibrutinib, have fewer side effects than traditional chemotherapy. However, as the drug is usually taken for several years, these side effects can be a burden.

There is some evidence that, if ibrutinib is taken for several years, the CLL is more likely to become resistant to this treatment. STATIC will investigated whether having a break from ibrutinib treatment will work as well as continuing treatment without a break, if whether taking a break from ibrutinib reduces side effects, whether it lowers the risk of CLL becoming resistant to ibrutinib, and whether there is any difference in the overall cost of CLL treatment. We also want to know whether having a break from ibrutinib changes how patients are feeling emotionally.

Who can participate?
830 patients will be enrolled into the STATIC trial. These patients will be made up of patients who have been treated on the NHS with Ibrutinib as their second or subsequent treatment for their CLL as well as those who have been treated in another study called the FLAIR trial.

What does the study involve?
Patients in the randomisation trial will be randomly allocated to have either continuous or intermittent treatment with ibrutinib.
A small number of patients finishing FLAIR will be advised to continue ibrutinib as their CLL is not well controlled enough for them to take part in the randomised trial and they can continue ibrutinib treatment in STATIC without being randomised.

What are the possible benefits and risks of participating?
We hope that participants will be helped by taking part in this study, but we can't guarantee this. However, the information we get from this study will contribute to medical research and help us to improve future treatments for people who have ibrutinib treatment for their CLL. As we learn more about the effects of taking ibrutinib for longer periods of time, pausing ibrutinib for periods, and how this changes the side effects, this may lead to future changes in treatment for CLL patients.
The STATIC Randomised trial will help to understand whether pausing ibrutinib treatment when CLL is well controlled is as good as continuing ibrutinib without a break. Both the randomised trial and clinical need group will give us information about the effects of taking ibrutinib for a long time as well as the benefits and safety of ibrutinib.
Both participants who are randomised to continuous treatment and who enter the patient need cohort will receive treatment for longer periods than standard care, which may prolong the presence of side effects. Participants will be closely monitored and will attend regular outpatient appointments to monitor this, and the side effects can often be managed by lowering drug dose or taking supportive medication.
Participants randomised to the intermittent treatment may have concerns about pausing treatment. However, treatment will only be paused in the trial when a patient is in a good remission, which may last for some considerable time, and will resume treatment when there are early signs of CLL reappearing.

Where is the study run from?
University of Leeds (UK)

When is the study starting and how long is it expected to run for?
June 2022 to September 2031

Who is funding the study?
National Institute for Health and Care Research (NIHR) Health Technology Assessment programme (UK)
Janssen-Cliag (UK)

Who is the main contact?
Rhiannon Lambkin
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Study website
https://ctru.leeds.ac.uk/static/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2021-005854-27

IRAS number
1003615

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
HM21/142069, IRAS 1003615, CPMS 52879

Study information

Scientific Title
A randomised phase III trial comparing intermittent with continuous treatment strategies in chronic lymphocytic leukaemia (CLL)

Acronym
STATIC

Study objectives
Current study objectives as of 07/07/2025:
An intermittent treatment strategy using a BTK inhibitor (including ibrutinib or acalabrutinib) will reduce treatment-emergent resistance and thus be at least non-inferior to continuous treatment with regards to time to treatment strategy failure whilst reducing resource impact for the NHS and improving quality of life.

Previous study objectives:
An intermittent treatment strategy using ibrutinib, will reduce treatment-emergent resistance and thus be at least non-inferior to continuous treatment with regards to time to treatment strategy failure whilst reducing resource impact for the NHS and improving quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 10/08/2022, HRA and Health and Care Research Wales (HCRW) (Health Research Authority, 2 Redman Place, London, E20 1JQ, United Kingdom; Tel: N/A; approvals@hra.nhs.uk), ref: 1003615
2. Approved 03/08/2022, MHRA (10 South Colonnade, Canary Wharf, London, E14 4PU, United Kingdom; +44 (0)20 3080 6000; info@mhra.gov.uk), ref: 1003615

3. Approved 02/08/2022, Health Research Authority (REC), North East - York Research Ethics Committee (North East - York Research Ethics Committee, NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 (0)207 104 8079; york.rec@hra.nhs.uk), ref: 1003615

Study design
STATIC is designed with multiple pathways, the 'Randomization Pathway' and the 'Clinical Need Cohort', which route a participant enters will be determined by their eligibility.

Randomisation Trial: A prospective, national, multicentre, open-label, randomized, controlled, two-arm, parallel-group, non-inferiority, Phase III trial to assess whether patients with CLL on long-term treatment with a BTK inhibitor (including ibrutinib or acalabrutinib) have similar disease control with an intermittent treatment strategy (experimental arm) compared with standard continuous treatment (control arm).

Clinical Need Cohort: A prospective, national, multicentre, open-label, single-arm, non-randomized cohort to assess the safety and overall survival of patients with CLL receiving long-term continuous treatment with ibrutinib.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Chronic lymphocytic leukaemia (CLL)

Interventions
Current interventions as of 07/07/2025:
In the randomisation pathway, participants will be randomised 1:1 to either intermittent treatment with a BTK inhibitor, known as the 'pausing treatment' arm, or continuous treatment. Participants randomised to continuous treatment will receive either ibrutinib (oral) 420 mg per day (or other reduced dose, if that dose has been stable for the past 6 months and there are no unresolved toxicities) or acalabrutinib (oral) 200 mg per day (or other reduced dose, if that dose has been stable for the past 6 months and there are no unresolved toxicities), until strategy failure, defined as active disease as per 2018 iwCLL criteria, death, or the end of the trial.

Participants randomised to the 'pausing treatment' arm (intermittent treatment strategy) will pause BTK inhibitor treatment immediately following randomisation, and restart when the restart criteria are met. When treatment restarts, participants restart BTK inhibitor treatment at

the standard dose (or their previous stable reduced dose) until the treatment pausing criteria are met. The pausing and resuming criteria are assessed locally every 3 months at standard clinic visits. Participants can pause and restart treatment multiple times until treatment strategy failure (defined as active disease per 2018 iwCLL criteria) whilst on treatment, death, or end of the study.

In the Clinical Need Cohort all participants will receive ibrutinib (continuous treatment), either at the recommended starting dose or the stable reduced dose they were receiving at the end of the FLAIR or IcICLLe trial, but will not be randomised. Participants in the Clinical Need Cohort will receive treatment during the trials 6 6-year recruitment period and for the 3 years of follow-up, meaning that participants will be on the trial for between 3-9 years, depending upon when they enter the trial.

Previous interventions:
In the randomisation pathway participants will be randomised 1:1 to either intermittent ibrutinib, known as the 'pausing ibrutinib' arm, or continuous ibrutinib treatment. Participants randomised to continuous treatment will receive ibrutinib (oral) 420 mg per day (or other reduced dose, if that dose has been stable for the past 6 months and there are no unresolved toxicities) until strategy failure, defined as active disease as per 2018 iwCLL criteria, death, or the end of the trial.

Participants randomised to the 'pausing ibrutinib' arm (intermittent treatment strategy) will pause ibrutinib treatment immediately following randomisation, and restart when the restart criteria are met. When treatment restarts, participants restart ibrutinib treatment at the standard dose (or their previous stable reduced dose) until the treatment pausing criteria are met. The pausing and resuming criteria are assessed locally every 3 months at standard clinic visits. Participants can pause and restart treatment multiple times until treatment strategy failure (defined as active disease per 2018 iwCLL criteria) whilst on treatment, death, or end of the study.

In the Clinical Need Cohort all participants will to receive ibrutinib (continuous treatment), either at the recommended starting dose, or the stable reduced dose they were receiving at the end of the FLAIR trial, but will not be randomised. Participants in the Clinical Need Cohort will receive treatment during the trials 6 year recruitment period and for the 3 years of follow up, meaning that participants will be on the trial for between 3-9 years, depending upon when they enter the trial.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Ibrutinib (Imbruvica), acalabrutinib (Calquence)

Primary outcome measure
Time to treatment strategy failure. Time to treatment strategy failure is defined as the time from randomisation to time of treatment strategy failure. Treatment strategy failure is defined as the first documented instance of active disease that does not respond to treatment, or death from any cause measured using patient records throughout the study

Secondary outcome measures
1. Overall survival will be measured for the randomisation trial as the time from randomisation to the time of death from any cause. In the clinical need cohort this will be calculated as the time from registration to the time of death from any cause.
2. Toxicity and tolerability based on adverse events, as graded by CTCAE V5.0 and determined by routine clinical assessments at each centre.
3. Cost-effectiveness is defined as a cost per incremental QALY below £20,000 and/or a positive incremental net monetary benefit. The cost-effectiveness of treatment options will be evaluated with respect to this criteria.
4. Quality of life will be assessed using the patient-reported outcome measures: EORTC-QLQ-C30, EORTC-QLQ-CLL and EQ-5D-5L. This will be measured in the randomisation trial only and will be recorded at baseline and after 3, 6 12, 18, 24, 30, 36 and 48 months of trial treatment.
5. Summative treatment-free Interval is defined as the time to treatment strategy failure, excluding any time spent on treatment.
6. Response to retreatment in intermittent treatment arm will be assessed as a patients response (partial remission (PR), stable disease (SD) or progressive disease (PD) according to the response criteria defined by the standard 2018 iwCLL criteria) between 9 and 12 months after restarting treatment.
7. Time to next treatment is defined as the time from randomisation to the start date of the next line of treatment. For the Clinical Need Cohort, this will be time from registration to the start date of the next line of treatment.
8. Response to next treatment for CLL will be assessed as the best response (PR, SD or PD according to the response criteria defined by the standard 2018 iwCLL criteria) achieved by a participant at any timepoint.
9. Rate of resistance mutation between trial arms will be assessed as the proportion of participants in each arm with a detectable BTK mutation at baseline, 24 months and 48 months for all randomised participants, and at 12, 36 months for those participants in whom a BTK mutation is detected.
10. Evolution of resistant sub-clones will be assessed as the proportion of BTK mutations that are identified over time. It will be assessed at baseline and following 24 and 48 months of trial treatment. If resistant subclones are present, biobank samples collected at 12 and 36 months of trial treatment, will be used to identify the onset of these subclones.

Overall study start date
21/06/2022

Completion date
01/09/2031

Eligibility

Key inclusion criteria
Current inclusion criteria as of 07/07/2025:
Trial Registration Inclusion Criteria:
1. At least 18 years old
2. A diagnosis of chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) (by 2018 iwCLL criteria)
3. World Health Organisation (WHO) performance status (PS) of 0,1 or 2
4. Biochemical values must be within the following limits within 4 weeks prior to randomisation /or registration for the Clinical Need Cohort and at baseline:
4.1. Alanine aminotransferase (ALT) ≤3 x upper limit of normal (ULN) OR Aspartate

aminotransferase (AST) ≤3 x ULN.
4.2. Total bilirubin ≤1.5 x ULN, unless bilirubin rise is due to Gilbert's syndrome or of non-hepatic origin
5. Agree to follow the pregnancy prevention plan*
6. Able to provide informed consent
*Participants randomised to the pause/resume arm must adhere to this whilst receiving treatment with a BTK inhibitor, but will not be required to follow contraceptive measures during the planned treatment breaks

Additional inclusion criteria for participants in the Clinical Need Cohort:
1. Meet all of the Registration Inclusion criteria
2. Currently receiving ibrutinib and nearing the end or having completed 6 years of ibrutinib treatment on FLAIR or IcICLLe**
3. Have signs of progressive or returning CLL after completing 6 years of ibrutinib treatment within FLAIR or IcICLLe, but prior to entry into STATIC

Additional inclusion criteria for Front Line participants entering the randomisation trial:
1. Meet all of the Registration Inclusion criteria
2. Currently receiving ibrutinib in FLAIR or IcICLLe, or having completed 6 years of ibrutinib of ibrutinib in FLAIR or IcICLLe**
3. In clinical remission all of the following:
3.1. No palpable lymph nodes;
3.2. No palpable spleen; and
3.3. Lymphocyte count below 5x10^9/L continuously for at least 12 months before randomisation
**Patients should enter STATIC on completion of treatment in FLAIR or IcICLLe, with no break in therapy, with the exception of participants who have completed the 6 years of treatment in FLAIR or IcICLLe prior to STATIC opening

Additional inclusion criteria for Previously Treated participants entering the randomisation trial:
1. Meet all of the registration inclusion criteria
2. Currently receiving ibrutinib or acalabrutinib for at least the previous 36 months as the second or subsequent line of treatment. There is no restriction on maximum duration of treatment prior to enrolment.
3. In clinical remission fulfilling all of the following:
3.1. No palpable lymph nodes;
3.2. No palpable spleen; and
3.3. Lymphocyte count below 5x10^9/L at the time of assessing eligibility

Previous inclusion criteria:
Trial Registration Inclusion Criteria:
1. At least 18 years old
2. A diagnosis of chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) (by 2018 iwCLL criteria)
3. World Health Organisation (WHO) performance status (PS) of 0,1 or 2
4. Biochemical values must be within the following limits within 4 weeks prior to randomisation /or registration for the Clinical Need Cohort and at baseline:
4.1. Alanine aminotransferase (ALT) ≤3 x upper limit of normal (ULN) OR Aspartate aminotransferase (AST) ≤3 x ULN.
4.2. Total bilirubin ≤1.5 x ULN, unless bilirubin rise is due to Gilbert's syndrome or of non hepatic origin
5. Agree to follow the pregnancy prevention plan*

6. Able to provide informed consent
*Participants randomised to the pause/resume arm must adhere to this whilst receiving ibrutinib, but will not be required to follow contraceptive measures during the planned treatment breaks

Additional inclusion criteria for participants in the Clinical Need Cohort:
1. Meet all of the Registration Inclusion criteria
2. Currently receiving ibrutinib and nearing the end or having completed 6 years of ibrutinib treatment on FLAIR**
3. Have signs of progressive or returning CLL after completing 6 years of ibrutinib treatment within FLAIR, but prior to entry into STATIC

Additional inclusion criteria for Front Line participants entering the randomisation trial:
1. Meet all of the Registration Inclusion criteria
2. Currently receiving ibrutinib in FLAIR or having completed 6 years of ibrutinib of ibrutinib in FLAIR**
3. In clinical remission all of the following:
3.1. No palpable lymph nodes;
3.2. No palpable spleen; and
3.3. Lymphocyte count below 5x10^9/L continuously for at least the 12 months before randomisation
**Patients should enter STATIC on completion of treatment in FLAIR, with no break in therapy, with the exception of participants who have completed the 6 years of treatment in FLAIR prior to STATIC opening

Additional inclusion criteria for Previously Treated participants entering the randomisation trial:
1. Meet all of the registration inclusion criteria
2. Currently receiving ibrutinib for at least the previous 36 months. There is no restriction on maximum duration of treatment prior to enrolment.
3. In clinical remission fulfilling all of the following:
3.1. No palpable lymph nodes;
3.2. No palpable spleen; and
3.3. Lymphocyte count below 5x10^9/L continuously for at least the 12 months before randomisation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
830

Key exclusion criteria

Current exclusion criteria as of 07/07/2025:
Trial Registration Exclusion Criteria:
1. Pregnant females
2. Known intolerance or hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption.
3. Receipt of live vaccination within 4 weeks prior to registration and for the duration of the study.
4. History or current evidence of Richter's transformation
5. Major surgery within 4 weeks prior to randomisation/or registration for the Clinical Need Cohort
6. Active infection
7. Concomitant warfarin (or equivalent vitamin K inhibitor)
8. Central nervous system involvement with CLL
9. Cardiac failure; including symptomatic cardiac failure not controlled by therapy, or unstable angina not adequately controlled by current therapy (in patients with a significant cardiac history the left ventricular function should be assessed and patients with severe impairment should be excluded)
10. Respiratory impairment (e.g. bronchiectasis or severe COPD)
11. Other severe, concurrent diseases or mental disorders that could interfere with their ability to participate in the study
12. Positive serology for Hepatitis B (HB), defined as a positive test for HBsAg. In addition, if negative for HBsAg but HBcAb positive (regardless of HBsAb status),aHB DNA test will be performed and if positive, the patients will be excluded. During treatment, these participants should be monitored and managed to prevent HBV reactivation.
13. Positive serology for Hepatitis C (HC) defined as a positive test for HCAb, in which case reflexively perform a test for hepatitis C RNA (for example, HCV RNA PCR). If positive, the patients will be excluded.
14. Persisting severe pancytopenia (neutrophils <0.5 x 109/L or platelets <50 x 109/L)unless due to direct marrow infiltration by CLL
15. Current treatment with prednisolone of >20mg/day
16. Uncontrolled Active haemolysis
17. History of stroke or intracranial haemorrhage within 6 months prior to enrolment.
18. Requirement for treatment with a strong CYP3A inhibitor or inducer
19. New treatment with two or more antiplatelet drugs, treatment that has been administered at a stable dose for at least 3 months prior to registration is permissible

Additional exclusion criteria for participants in the Clinical Need Cohort:
1. Meet none of the registration exclusion criteria
2. Active Disease, as per the 2018 iwCLL criteria requiring an alternative therapy.
3. Received treatment other than ibrutinib for CLL since completing FLAIR
4. Be eligible for front-line randomisation
5. Ibrutinib treatment break for toxicity/patient choice for more than 28 days in the last 12 months (added 07/11/2024)

Additional exclusion criteria for Front-Line participants entering the randomisation trial:
1. Meet any of the registration exclusion criteria
2. Disease progression (according to 2018 iwCLL criteria)
3. Ibrutinib treatment break for toxicity/patient choice for more than 28 days in the last 12 months

Additional exclusion criteria for Previously Treated participants entering the randomisation trial:
1. Meet any of the registration exclusion criteria

2. Disease progression (according to 2018 iwCLL criteria)
3. Ibrutinib or acalabrutinib treatment break for toxicity/patient choice for more than 28 days in the last 12 months
4. Any illness, disease or condition, such as active cancer or secondary primary malignancy (SPM), with a prognosis of less than 5 years
5. Patients with a creatinine clearance of less than 30ml/min (either measured or derived by the Cockcroft Gault formula or an alternative locally approved formula).

Previous exclusion criteria:
Trial Registration Exclusion Criteria:
1. Pregnant females
2. Known intolerance or hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption.
3. Receipt of live vaccination within 4 weeks prior to registration and for the duration of the study.
4. History or current evidence of Richter's transformation
5. Major surgery within 4 weeks prior to randomisation/or registration for the Clinical Need Cohort
6. Active infection
7. Concomitant warfarin (or equivalent vitamin K inhibitor)
8. Central nervous system involvement with CLL
9. Cardiac failure; including symptomatic cardiac failure not controlled by therapy,or unstable angina not adequately controlled by current therapy (in patients with a significant cardiac history the left ventricular function should be assessed and patients with severe impairment should be excluded)
10. Respiratory impairment (e.g. bronchiectasis or severe COPD)
11. Other severe, concurrent diseases or mental disorders that could interfere with their ability to participate in the study
12. Positive serology for Hepatitis B (HB) defined as a positive test for HBsAg. In addition, if negative for HBsAg but HBcAb positive (regardless of HBsAb status),aHB DNA test will be performed and if positive the patients will be excluded. During treatment, these participants should be monitored and managed to prevent HBV reactivation.
13. Positive serology for Hepatitis C (HC) defined as a positive test for HCAb, in which case reflexively perform a test for hepatitis C RNA (for example HCV RNA PCR). If positive the patients will be excluded.
14. Persisting severe pancytopenia (neutrophils <0.5 x 109/L or platelets <50 x 109/L)unless due to direct marrow infiltration by CLL
15. Current treatment with prednisolone of >20mg/day
16. Uncontrolled Active haemolysis
17. History of stroke or intracranial haemorrhage within 6 months prior to enrolment.
18. Requirement for treatment with a strong CYP3A inhibitor or inducer
19. New treatment with two or more antiplatelet drugs, treatment that has been administered at a stable dose for at least 3 months prior to registration is permissible
20. Current treatment with any concomitant ACE inhibitors

Additional exclusion criteria for participants in the Clinical Need Cohort:
1. Meet none of the registration exclusion criteria
2. Active Disease, as per the 2018 iwCLL criteria requiring an alternative therapy.
3. Received treatment other than ibrutinib for CLL since completing FLAIR
4. Be eligible for front-line randomisation
5. Ibrutinib treatment break for toxicity/patient choice for more than 28 days in the last 12 months (added 07/11/2024)

Additional exclusion criteria for Front-Line participants entering the randomisation trial:
1. Meet none of the registration exclusion criteria
2. Disease progression (according to 2018 iwCLL criteria)
3. Ibrutinib treatment break for toxicity/patient choice for more than 28 days in last 12 months

Additional exclusion criteria for Previously Treated participants entering the randomisation trial:
1. Meet none of the registration exclusion criteria
2. Disease progression (according to 2018 iwCLL criteria)
3. Ibrutinib treatment break for toxicity/patient choice for more than 28 days in last 12 months
4. Any illness,disease or condition,such as active cancer or secondary primary malignancy (SPM), with a prognosis of less than 5 years
5. Patients with a creatinine clearance of less than 30ml/min (either measured or derived by the Cockcroft Gault formula or alternative locally approved formula).

Date of first enrolment
13/10/2022

Date of final enrolment
01/09/2028

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

Study participating centre
St James's Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
Aberdeen Royal Infirmary
Foresterhill Road
Aberdeen
United Kingdom
AB25 2ZN

Study participating centre
Good Hope Hospital
Rectory Road
Sutton Coldfield
United Kingdom
B75 7RR

Study participating centre
Heartlands Hospital
Bordesley Green East
Bordesley Green
Birmingham
United Kingdom
B9 5ST

Study participating centre
Victoria Hospital (blackpool)
Whinney Heys Road
Blackpool
United Kingdom
FY3 8NR

Study participating centre
Bradford Royal Infirmary
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ

Study participating centre
Castle Hill Hospital
Entrance 3
Castle Road
Cottingham
United Kingdom
HU16 5JQ

Study participating centre
Christie Hospital
Wilmslow Road
Manchester

United Kingdom
M20 4BX

Study participating centre
Churchill Hospital
Churchill Hospital
Old Road
Headington
Oxford
United Kingdom
OX3 7LE

Study participating centre
Clatterbridge Hospital
Clatterbridge Hospital
Clatterbridge Road
Wirral
United Kingdom
CH63 4JY

Study participating centre
Derriford Hospital
Derriford Road
Plymouth
United Kingdom
PL6 8DH

Study participating centre
Grantham and District Hospital
101 Manthorpe Road
Grantham
United Kingdom
NG31 8DG

Study participating centre
The James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
Kent and Canterbury Hospitals NHS Trust
Ethelbert Road
Canterbury
United Kingdom
CT1 3NG

Study participating centre
Kettering General Hospital
Kettering General Hospital
Rothwell Road
Kettering
United Kingdom
NN16 8UZ

Study participating centre
Kings College Hospital
Mapother House
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Denmark Hill
London
United Kingdom
SE5 8AB

Study participating centre
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre
Lincoln County Hospital
Greetwell Road
Lincoln
United Kingdom
LN2 5QY

Study participating centre

Milton Keynes General Hospital
Milton Keynes Hospital
Standing Way
Eaglestone
Milton Keynes
United Kingdom
MK6 5LD

Study participating centre
Musgrove Park Hospital
Orthopaedic Triage Service
Parkfield Drive
Taunton
United Kingdom
TA1 5DA

Study participating centre
New Cross Hospital
Wolverhampton Road
Wolverhampton
United Kingdom
WV10 0QP

Study participating centre
Northampton
Northampton General Hospital
Cliftonville
Northampton
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NN1 5BD

Study participating centre
Nottingham University Hospitals NHS Trust - City Campus
Nottingham City Hospital
Hucknall Road
Nottingham
United Kingdom
NG5 1PB

Study participating centre

Pilgrim Hospital (nuh)
Sibsey Road
Boston
United Kingdom
PE21 9QS

Study participating centre
Poole
Poole Hospital
Longfleet Road
Poole
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BH15 2JB

Study participating centre
Princess Royal University Hospital
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Orpington
United Kingdom
BR6 8ND

Study participating centre
Queen Alexandras Hospital
Southwick Hill Road
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United Kingdom
PO6 3LY

Study participating centre
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Queen Elizabeth Hospital
Sherriff Hill
Gateshead
United Kingdom
NE9 6SX

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University Hospitals Birmingham NHS Foundation Trust
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Mindelsohn Way

Edgbaston
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United Kingdom
B15 2GW

Study participating centre
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Rom Valley Way
Romford
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RM7 0AG

Study participating centre
Rotherham District General Hospital
Moorgate Road
Rotherham
United Kingdom
S60 2UD

Study participating centre
Royal Bournemouth General Hospital
Castle Lane East
Bournemouth
United Kingdom
BH7 7DW

Study participating centre
Royal Cornwall Hospitals NHS Trust
Royal Cornwall Hospital
Treliske
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United Kingdom
TR1 3LJ

Study participating centre
Royal Devon University Healthcare NHS Foundation Trust
Royal Devon University NHS Ft
Barrack Road
Exeter
United Kingdom
EX2 5DW

Study participating centre
Royal Hampshire County Hospital (rhch)
Romsey Road
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United Kingdom
SO22 5DG

Study participating centre
Russells Hall Hospital
Pensnett Road
Dudley
United Kingdom
DY1 2HQ

Study participating centre
Salisbury District Hospital
Salisbury District Hospital
Odstock Road
Salisbury
United Kingdom
SP2 8BJ

Study participating centre
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
St. Bartholomews Hospital
West Smithfield
London
United Kingdom
EC1A 7BE

Study participating centre

St Georges
St. Georges Hospital
117 Suttons Lane
Hornchurch
United Kingdom
RM12 6RS

Study participating centre
Stoke Mandeville Hospital
Mandeville Road
Aylesbury
United Kingdom
HP21 8AL

Study participating centre
Torbay and South Devon NHS Foundation Trust
Torbay Hospital
Newton Road
Torquay
United Kingdom
TQ2 7AA

Study participating centre
University College London Hospitals NHS Foundation Trust
250 Euston Road
London
United Kingdom
NW1 2PG

Study participating centre
University Hospital Crosshouse
Kilmarnock Road
Kilmarnock
United Kingdom
KA2 0BE

Study participating centre
Monklands District General Hospital
Monkscourt Avenue

Airdrie
United Kingdom
ML6 0JS

Study participating centre
University Hospital of Wales
Heath Park
Cardiff
United Kingdom
CF14 4XW

Study participating centre
West Middlesex University Hospital
Twickenham Road
Isleworth
United Kingdom
TW7 6AF

Study participating centre
The Worcestershire Royal Hospital
Newtown Road
Worcester
United Kingdom
WR5 1ZL

Study participating centre
York Hospital
Wigginton Road
York
United Kingdom
YO31 8HE

Study participating centre
The Royal Marsden Hospital (surrey)
Downs Road
Sutton
United Kingdom
SM2 5PT

Study participating centre
Royal Shrewsbury Hospital
Mytton Oak Road
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United Kingdom
SY3 8XQ

Study participating centre
Ysbyty Gwynedd Hospital (yg NHS Trust)
Ysbyty Gwynedd
Penrhosgarnedd
Bangor
United Kingdom
LL57 2PW

Study participating centre
Wrexham Maelor Hospital
Croesnewydd Road
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Wrexham
United Kingdom
LL13 7TD

Study participating centre
Ipswich Hospital
Heath Road
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IP4 5PD

Sponsor information

Organisation
University of Leeds

Sponsor details
UoL / LTHT Joint Sponsor QA Office
Secretariat
University of Leeds
Woodhouse Lane
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Sponsor type
University/education

Website
http://www.leeds.ac.uk/

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Janssen-Cilag Limited

Funder Name
National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Data from this study will be published once trial end points have been reached and after the overall trial end date. Publication will be via peer reviewed journals as well as via presentations at conferences.

A summary of the study results and trial updates will also be shared with participants via the trial sites, patient forums, seminars and digital platforms , once the results have been published.

Intention to publish date
01/09/2032

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No